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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 10/032,108 | 12/20/2001 | Timothy David Osslund | 01017/38834F | 7916 |

7590 01/24/2006

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EXAMINER

BASI, NIRMAL SINGH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|------------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/032,108 | | OSSLUND, TIMOTHY DAVID | |
| | Examiner | | Art Unit | |
| | Nirmal S. Basi | | 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 62,66,75,76,79 and 81-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 62,66,75,76,79 and 81-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment filed 11/7/05 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 62, 66, 75, 76, 79 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw (US Patent 4,904,584).

Applicant argues Shaw does not describe making lysine modifications in specific tertiary structure components of GCSF let alone an external loop. Applicant's arguments have been fully considered but are not found persuasive. Shaw teaches that all but 1 to approximately 6 of the original lysines can be deleted and/or replaced (see column 3, first paragraph and second paragraph, column 8 and column 14. Shaw (US Patent 4,904,584) discloses the "site-specific homogenous modifications of polypeptides" as well as substitutions of lysine residues 16, 23 and 34 with arginine (see, e.g., cols. 9-10, Table2, listing modification of lysine residues at positions 16, 23, 14 and 40). The lysine residues 16, 23, 34 and 40 disclosed by Shaw correspond to lysine residues 17, 24, 35 and 41 of instant application. SEQ ID NO:2 of instant application

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contains the optional N-terminal methionine residue at position 1, in contrast Shaw teaches the G-CSF molecule disclosed in Figure 4, which does not contain the optional N-terminal methionine. As such, the numbering used by Shaw is one amino acid lower than that used in instant specification. Shaw also teaches the modification of proteins by replacing naturally occurring lysine residues with non-lysines, preferably arginine, and substituting a lysine for a non-lysine residue. Abstract, col. 3, lines 36-43. The reference teaches that such modification is performed so as to control the attachment site of a molecule, such as PEG, to the protein, Col. 1. Shaw further teaches that in addition to modification of G-CSF by substituting the lysine residues with arginine, and other lysine residue can be used for PEG attachment. Therefore since Shaw teaches the same mutations disclosed in claims 62-65 it meets the limitations of said claims, absent evidence to the contrary.

Claim Rejection, 35 U.S.C. 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 62, 66, 75, 76, 79 and 81-83 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 62 and 66 are indefinite because "at least one amino acid residue is/are altered" to include "one or more lysines amino acid residues" and not "at

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least on amino acid sequence" altered" to include "one or more lysines amino acid residues". The amino acid sequence could be letters on a page identifying the amino acid residues of a polypeptide.

Further claims 62 and 75 are rejected for use of "at least one helix A amino acid sequence", "helix C amino acid sequence" and "helix D amino acid sequence". It is suggested "at least one helix A amino acid sequence" be changed to "at least one amino acid residue contained in helix A", to overcome the rejection. The other changes should be made accordingly to overcome the rejection.

Claim 76 is rejected for use of "at least two of helix A amino acid sequence", "helix C amino acid sequence" and "helix D amino acid sequence". It is suggested "at least two of helix A amino acid sequence" be changed to "at least two amino acid residue contained in helix A", to overcome the rejection. The other changes should be made accordingly to overcome the rejection.

Claim 79 is rejected for use of "at least three of helix A amino acid sequence", "helix C amino acid sequence" and "helix D amino acid sequence". It is suggested "at least three of helix A amino acid sequence" be changed to "at least three amino acid residue contained in helix A", to overcome the rejection. The other changes should be made accordingly to overcome the rejection.

Claims 80-83 are indefinite for depending on an indefinite base claim and fail to resolve the issues raised above.

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4. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi
Art Unit 1646
1/23/06


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER